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Implant Failure: STRATOS® system for Pectus Repair.

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Abstract

Background: Three European centres have recently reported dramatic failures of STRATOS® titanium system, approved in Europe and United States of America since 2007 and meant for pectus repair, without detailed exploration of its causes.

Methods: Failed implants (fractures or loosened crimp connectors) were surgically explanted from 12 patients and biopsies taken from surrounding discoloured tissue. Detailed failure analysis performed to find the cause of failures. Inductively coupled mass spectroscopy, scanning electron microscopy and energy dispersive X-ray spectroscopy was used for determine Titanium and visualize Titanium wear debris in histological sections.

Results: Implants failed in all patients via fracture of connecting bar, fracture of lateral bar at reduced cross-section, loosening of crimp connector or, different combinations. All fracture surfaces were clean and smooth without any signs of plastic deformation. Failure already started at 10 months post-implantation and continued till 2.5 years. Biopsy of discoloured tissue around the failures showed 0.4 to 105 mg of Titanium per gram tissue and close observation showed presence of Titanium wear debris.

Conclusions: Combined tensile, compressive, bending and, torsional loading on the implant during each breathing cycle caused loosening and fatigue fractures, which led to failure. Excessive rubbing at the fracture and loosening site caused the release of large amounts of Titanium in the surrounding tissue which may lead to metallosis. Presence of long and sharp pieces of failed implant in the

cardio-thoracic region is a grave danger to vital organs. All patients should be closely followed and all implants should be removed in our opinion. Serious reconsideration for clinical use of this implant is necessary.

Introduction.

Prosthetic science and technology have come a long way since the earliest reports of an artificial metallic leg placed in the Vedic period(1). Prosthetic failure, though, can have catastrophic effects on quality of life. The failure of 400 zirconia femoral heads in 2001(2) and silicone breast implant recall in 2010(3) are a few of such examples.

The Ravitch technique is currently used for complex Pectus deformities, the Nuss procedure having evolved to being the standard for more symmetric Pectus deformities. The STRATOS® titanium system (Strasbourg Thoracic Osteosyntheses System; MedXpert, Heitersheim, Germany) was introduced commercially in 2007 as a permanent stabilization and was designed not to need removal(4). The STRATOS® system (Figure 1) was advertised for both Pectus repair and for reconstruction after chest wall resection or trauma. The system is approved both in Europe and the USA¹.

Long term results, are lacking, as a search of the literature results in only a dozen papers reporting on small series, almost all dealing with repair after chest wall resection(5), very few on pectus repair. The only exception is a paper by Berthet and colleagues who reported in 2015 in this journal, failure in about half of their 25 pectus patients at a mean follow-up of 20.2 months (6). We were alerted by a patient presenting with sudden intense pain after hearing a “snapping” sound in her chest. The symptoms proved to be caused by a fracture of a titanium connecting bar. All implantations were performed in the usual fashion for

¹ FDA approval on 24 June 2008 under number K073556 via a 510(k) pathway application. EC certification by Notified Body 0483, mdc medical device certification GmbH, Stuttgart, Germany.

supported Ravitch operations, although the instructions supplied by the manufacturer were scarce, nor was there any relevant literature available. After we had experienced a number of failures, we alerted the national Health Care Inspectorate, the manufacturer and all cardio-thoracic surgeons in the country. We never used the STRATOS system in chest wall reconstruction.

This report describes all 12 patients that we operated utilizing the STRATOS® system, analyses the causes for failure of the system, and the consequences.

Materials and Methods.

Materials.

The STRATOS® system is composed of rib clips that are fixed to the ribs, bars connecting the rib clips either for stability in pectus correction forces or for rib cage reconstruction. Rib clips are fixated to the connecting bars with the help of crimp connectors (Fig. 1). One or more of these sets consisting of bar and two clips can be implanted. The STRATOS® system was sold to function as a permanent implant.

Patients.

We used the STRATOS® system in 12 patients (4 female, 8 men) with chest wall deformities from 14 December 2011 until 18 July 2013. Ages ranged from 14 to 71 years; median of 18.5. There were 7 with pectus excavatum, 4 with pectus carinatum and 1 with a combination. The indications for surgery were mostly a mixture of cosmetic and somatic complaints.

Operation.

Essentially the operation was conducted as had been done for decades whence stainless steel Rehbein bars were used for support of the chest wall. The Rehbein bars were all removed after one year postoperatively, while the STRATOS system was sold to remain implanted. For male patients a median incision was used and for female patients a submammary incision. All muscle was dissected free of the chest wall until the bony parts of the ribs was reached. The rectus abdominal muscles were dissected free of the costal arch. Excess chondrous rib were resected. The sternum was divided at one or two locations so as to release tension in the anatomical position. The sternum was then fixated with steel wire. The clips were attached to the ribs and were connected with the bars and the crimp connectors were squeezed shut with the supplied tool. Three of the 12 patients had two sets of bar and clips implanted, while in 3 of the 9 other patients that had a single set, the connecting bar was placed posterior to the sternum.

The ribs were reconnected with the sternum with absorbable suture. The sternum was fixated to the connecting bar(s) with steel wire.

Radiology

Chest posteroanterior roentgenograms were done after implantation and at time of complaints of a recall visit whence they were reviewed by a radiologist. Implant failure was diagnosed if at least one of the following criteria was present:

- a. fracture of the connecting bar (Fcb).
- b. loosening and/or fracture of the crimp connector, that was diagnosed if the bar was displaced without fracture, or the crimp connector's shape was deformed during the follow-up X-ray. (Lcc).
- c. fracture of the lateral bar at reduced cross-section (Frc).

Explantation.

Detaching the crimp connectors from the ribs was hampered because the connectors were not designed to be taken out. To insert a lever between the rib and the connector could take substantial force. Samples were taken of discoloured tissue surrounding material fractures.

Failure Analysis

All the explanted bits and pieces were analysed at the department of biomedical engineering. Close up pictures were taken with a stereo microscope (Wild M 7 S, Heerbrugg, Switzerland) mounted with a Canon EOS 30D camera of the failures. Some fracture surfaces were also observed under the Scanning electron microscope (Philips XL30FEG) at higher magnifications.

Visualization of Titanium wear debris

Biopsy tissue was fixated by placement in a 2% paraformaldehyde solution. The tissue was later sectioned into microscopic slices. The slices were placed on a glass slide to be observed directly under the phase contrast microscope. Some of the slices were also observed under the scanning electron microscope and Energy Dispersive X-ray spectroscopy (EDX) was performed to locate the Ti debris.

Inductively Coupled Mass Spectroscopy Measurements

Sample preparation: The tissue was dried and 100 mg was heated in 2.5 ml destruction solvent (nitric acid / perchloric acid / sulphuric acid = 4/1/1) at 60°C during 24 hours until a clear solution was obtained. This mixture was diluted to 10.0 ml with ultrapure water (solution A) in a polypropylene container. A blank sample in identical fashion (solution A_b) was used as negative control. Calibration and internal standard solutions (C) were prepared appropriately.

Assay: 100 microliter of each calibration solution was diluted with 5 ml solution C and to each solution, 100 microliter solution A_b was added. 100 microliter of each sample solution (A) was diluted with 5 ml solution C and to each solution; 100 microliter ultrapure water was added. Samples were mixed and measured on a Varian 820 MS ICP mass spectrometer.

Results.

One patient complained of chest pain in concert with a rasping sound in her chest 4 months after implantation. Chest X-ray showed that one of the crimp

connectors between the connecting bar and rib clip was loose, which was repaired operatively (patient 8). This patient later developed 2 Frc's on the contralateral side. Nine months after the last implantation, on 29th April 2014, we were alerted by our third patient in sequence who felt severe chest pains after hearing a snapping sound, without any noticeable eliciting event. Chest X-ray showed Frc of one of the two sets of material implanted (Fig 2). This incident caused us to recall all the patients for review. In 10 out of 12 (83%) patients already had broken implants with single or multiple points of failure were detected on the X-ray (Figure 2). In the remaining 2 out of 12 patients the fracture was detected only at operation, because the fracture was obscured by steel wires, while in the last patient the crimp connector's failure (loosening) only appeared on metallurgic examination in the form of signs of excessive rubbing and wear. Only 4 out of the 12 patients complained of pain, sudden, chronic or intermittent (Table 1). In one patient there was considerable displacement of the connecting bar (Fig 2b). In order to prevent the chance of translocation of the broken parts of implants and damage to cardio- thoracic organs, the implants were removed from all patients. Often during the removal surgery blackened tissue (Fig. 6b) was observed in the vicinity of the failure points of the Stratos implant, thus biopsies were taken from this area in 6 of the last 7 patients that underwent explantation. Two patients chose to have the implants removed electively one of which then proved to have a broken connecting bar and the other showed loosening of the crimp connector both of which were not detected on X-ray. The explants were cumbersome the rib clips clearly not being designed for easy explantation.

Table 1 presents the list of all the failures found in each explanted Stratos implant, the supporting material contains post-retrieval photos of all the implants listed in Table 1.

The 15 implants had 30 joints where the connecting bars were held in place by 30 crimp connectors. 7 out of the 30 joints (23%) showed Lcc and close analysis of these connectors showed severe rubbing of the connecting bar against the crimp connector (Fig. 4b) with clear metallic mass loss and sometimes also fracture of the crimp connector.

Of 15 connecting bars 7 were fractured, Fcb (47%) (Fig. 4a) and 10 of 30 rib clips (33%) were fractured at the spot of reduced cross-section, Frc (Fig. 4c). None of the fractures showed any signs of plastic deformation. High amounts of Titanium were found in the blackened tissue around the failure points (Table 1), further analysis showed that this Titanium is present in the form of debris aggregated at localized spots in the tissue (Fig 6).

Kaplan Meier analysis shows that all Stratos implants failed from 4 months to 2½ years postoperatively (Fig 3). The graph shows a fairly steady rate of fracture up to 2 years postoperatively, whence about half of the patients have experience a fracture. In the half year thereafter, the remaining half of the patients experienced a fracture. There is no demonstrable difference between usage of two instead of 1 bar. The series is too small to demonstrate any difference between pre- or post-sternal implantation

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Careful examination of the radiographs showed all fractures or loosening's although sometimes radiographs from two different time points needed to be compared to see slight amounts of sliding. One particular fracture of a connecting bar was not visible at the first glance due to clutter of the image because of steel wires although in retrospect a slight kink in the bar was observed. The radiographs and photographs of explanted material from all patients can be seen in supplementary information (Supplemental figures S1 to S12).

Titanium levels in the 6 biopsies ranged from 0.4 to 10.5 mg per gram tissue (Table 1).

In the meantime 2 patients have had a repeat procedure to implant a Nuss bar, because the deformity had relapsed.

Discussion.

This study shows all Stratos systems to fail for pectus repair. Therefore, we deem the system unsuitable for this purpose and should be taken off the market for this indication. We have no opinion on its performance for other indications than for pectus repair. The Stratos system was initially reported at the 2007 EACTS annual meeting in a presentation of 14 cases, by the inventor. Thereafter there is no paper by the inventor on these 14 cases or on any other group of pectus patients. Most literature is on reconstruction of the chest wall after chest wall resections. At its introduction in 2007 it was advertised that the system was designed to be left implanted where an X-ray of a reconstructed chest wall is depicted using two bars, without reference to any evidence or recommendation.

In the next version of the brochure in 2013 it was still maintained that the material could remain in the body indefinitely and shows an X-ray of a reconstructed chest wall using three bars, again without evidence as to its merit. A brochure from 2015 (in Dutch) was sent to us that very year, in which the usage of three bars was advised, again without supporting evidence as to the efficacy of this strategy.

Stefani in 2013(7) showed the use of 1 bar for pectus excavatum repair in two 20 year old patients, within 2.5 years one of the patient showed a fractured bar. The implant was removed and the patient showed recurrence of the deformity in a 12 months period. The failure was located at the rib clip in the region with the hole in the bar, which is different from any of the failures reported in this study. A recent study by Berthet from two European hospitals(6) shows the same three types of failures observed by us when they used the STRATOS system for rib osteosynthesis in about a 4 year period. Berthet did not go into the mechanistic causes of the failure of this material, which is now elucidated by this very study. As Berthet's group used also another titanium osteosynthesis system of totally different design, but similar proportions, we suggest that titanium of this proportion is not appropriate for this indication. We showed that the survival rate of the implants does not get any better when we use 2 instead of 1 implant, thus it is debatable if evolving on to minimum 3 bars will show an increase in implant survival rate, although this would need systematic study. From a mechanistic standpoint it is unlikely that increasing the number of bars to three will solve this problem, due to the very nature of the failure. Movement through respiration will obviously remain and as these fractures are doubtlessly due to

fatigue of the material, the problem will not be solved in our conviction.

Furthermore just a slight increase in survival rate of the implant using 3 bars is not enough to justify its continued clinical use as a permanent implant, not needing removal, as long as we cannot show that the implant is safe and no failure can be expected in future.

Our findings indicate to fatigue as the mechanism for crack initiation and fracture of the connecting bars (F_{CB}) and rib clip (F_{RC}) by growth of the crack at each cycle of loading. Fatigue requires application of cyclic loading, in this case bending caused by breathing, which causes failure without any plastic deformation. Thus fatigue is, qua mechanism, different from failure under continuous loading (overload). Under the overload situation the material would first deform plastically and then fail, this can be clearly distinguished on examination of the fracture. Fatigue as a mechanism means that the implant design brings the material, at certain locations of the implant, under cyclic stresses which are larger than the material's fatigue limit. The STRATOS implants seemed to have come under heavy combined loading during the activity of breathing (Fig. 5). Immediately after implantation the rib clips held the implants tightly in place but during each breathing cycle the implant material would have experienced cycles of tensile and compressive stresses in combination with bending and torsional loads (Fig. 5). Estimation of the exact amounts of these stresses would remain impossible but it is clear that the normal loads (tension and compression) could cause the rubbing and sliding at the crimp connector - connecting bar interface, whereas the bending and

torsional moment could cause opening of the crimp connector resulting in loosening. The same tensile, bending and torsional loading was able to initiate a fatigue crack in the connecting bars (F_{CB}) or rib clip (F_{RC}) which grew rapidly to give rise to implant failure, although we were not able to see this process of crack initiation and growth during the follow-up X-rays. The fact that all the fractures were clean (Fig. 4 a, c, d, e) i.e. without any sign of plastic deformation in a ductile material such as Titanium, and the presence of Titanium ions (Table 1) and debris (Fig. 6) in the surrounding tissue indicates strongly to fatigue failure mechanism. Titanium ions and debris around both the loosening and failures sites of the implant indicates large amount of friction and wear during either the process of loosening (Fig. 4b), crack growth (Fig. 5) or, when the two loosened or failed end of the implant were lying next to each other before retrieval (Fig. 6b).

Presence of multiple failures on the same implant e.g. two loosening, two fractures or loosening with fracture indicates that one failure was not able to completely relieve the stresses in the implant and prevent the next failure. For implants with two loosening (patient no. 6 and 7) we can expect that both the loosening were initiated almost in the same time period, because if one loosening would initiate and allows for sliding then this would relieve the normal stresses (tensile or compression) and will prevent initiation of a second loosening. On the other hand initiation of loosening would not relieve the bending and torsional loading on the other parts of the implant hence would not prevent initiation of a crack and growth to fracture (patients no. 1, 5 and 6). Presence of two fractures (patients no. 4, 12 and 12) on the same implant

indicates that initiation of a crack or complete fracture does not prevent initiation of a crack and its growth on a second site on the same implant. The reason here could be the use of extra tie wires which are placed for better immobilization of the implant, which would still keep part of the broken implant closely attached to the ribcage transferring its motion during each breathing cycle allowing for crack initiation and fracture on a second site.

Although estimation of the fatigue life of the implant is difficult, the first few fractures took place at about 10 months (Fig. 3) thus the crack initiation and fracture took about 8.5 million cycles, assuming an average respiration rate of 20 breaths per minute. STRATOS manufacturers provide 6 advantages in their information brochure for the use of pure titanium over stainless steel but fatigue resistance is not part of it. Comparing 8.5 million cycles to the standard fatigue life curve for pure, cold rolled, grade 3 titanium(8) shows that the implants are enduring more than 300 MPa of combined load.

The clinical consequences of the presence of Ti and Ti debris along with freely floating implant pieces in the thoracic area could possibly impact negatively on the patient's wellbeing leading to metallosis (9) which is an ill-defined condition described after orthopaedic surgical implants elsewhere in the body.

Failed STRATOS implant also brings the danger of loose and migrating long pieces of metal with sharp ends in the cardiothoracic region (Fig. 2a and b) with the vital blood carrying vessels and organs like heart and lung. A recent study reported migration of a pectus bar through the tricuspid valve into the right atrium of the heart damaging the right coronary artery and posterior leaflet of the tricuspid valve on the way(10).

Why we introduced the STRATOS system at all in our clinic is because the traditional Rehbein stainless steel bars proved less effective in pectus carinatum and arcuatum, while the STRATOS system with its rib clips seemed to provide for more stability, particularly in those varieties of chest wall deformity. At the time we were in a gradual process of transition to the Nuss bars, but again, these seemed to be less well suited for chest wall deformities other than symmetric pectus excavatum. We were surprised that no other cardio-thoracic surgeons in our country had used the STRATOS system for pectus deformity. In addition, we received no active response from the national Health Care Inspectorate.

In conclusion, despite approval by responsible organizations in Europe and USA we show that the STRATOS implant and material used is not suitable for pectus repair as it shows fatigue fractures in virtually all cases and is not well designed for easy explanation. Furthermore, we advise close follow-up of patients with implanted STRATOS material, including X-rays.

For all future use the Ti implant design should be changed so that the maximum stress active on the implant *in vivo* should be much lower than 300 MPa.

Financial Disclosures: None of the authors have a financial disclosure.

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Tables

Table 1. Different types of failures observed in explanted Stratos implants placed in 12 patients for Pectus correction. **F_{CB}** is the fracture in the connecting bar, **L_{CC}** is loosening and failure of crimp connector, **F_{RC}** is fracture in rib clip at reduced cross-section, * indicates simultaneous tissue biopsy and the last column contains the amounts of Ti determined by Atomic absorption spectroscopy. This table summarizes all the figures from the supporting material.

Patient	N bars	Symptoms	N fractures	F_{CB}	L_{CC}	F_{RC}	mg Ti per g tissue	Interval between implantation and diagnosis (days)	Recurrence after removal
1*	1	no	2	1	1	0	10.5	896	no
2	1	no	1	0	0	1		862	no
3	2	sudden pain	1	0	0	1		817	no

4*	1	no	2	1	0	1	0.4	840	no
5*	1	no	2	0	1	1	2.0	792	no
6*	1	no	3	0	2	1	1.5	660	no
7	1	intermittent pain	2	0	2	0		583	no
8	2	chronic pain	2	0	0	2		118	yes, reoperated with Nuss bar
9	1	chronic pain	1	1	0	0		231	yes, reoperated with Ravitch procedure

10*	1	no	2	1	1	0	1.0	776	yes, declined reoperation
11	1	no	1	0	1	0		387	no
12*	2	no	4	3	0	1	1.6	314	yes, reoperated with Nuss bar
Total	15		23	7	8	8			

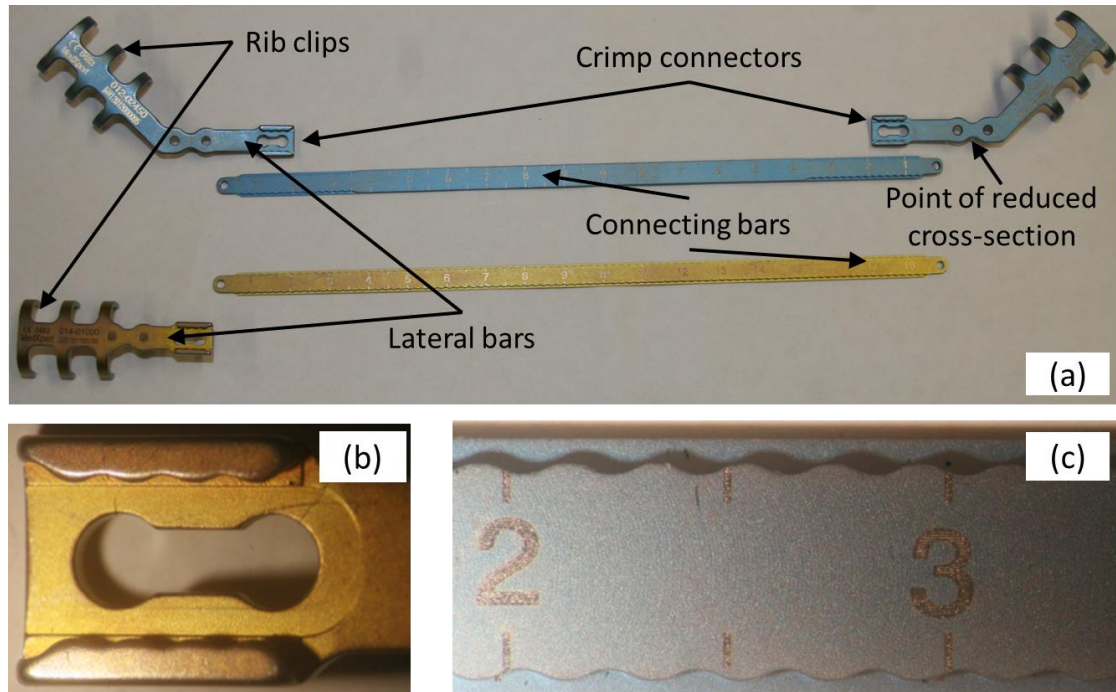


Figure 1. Different parts of the STRATOS Implant

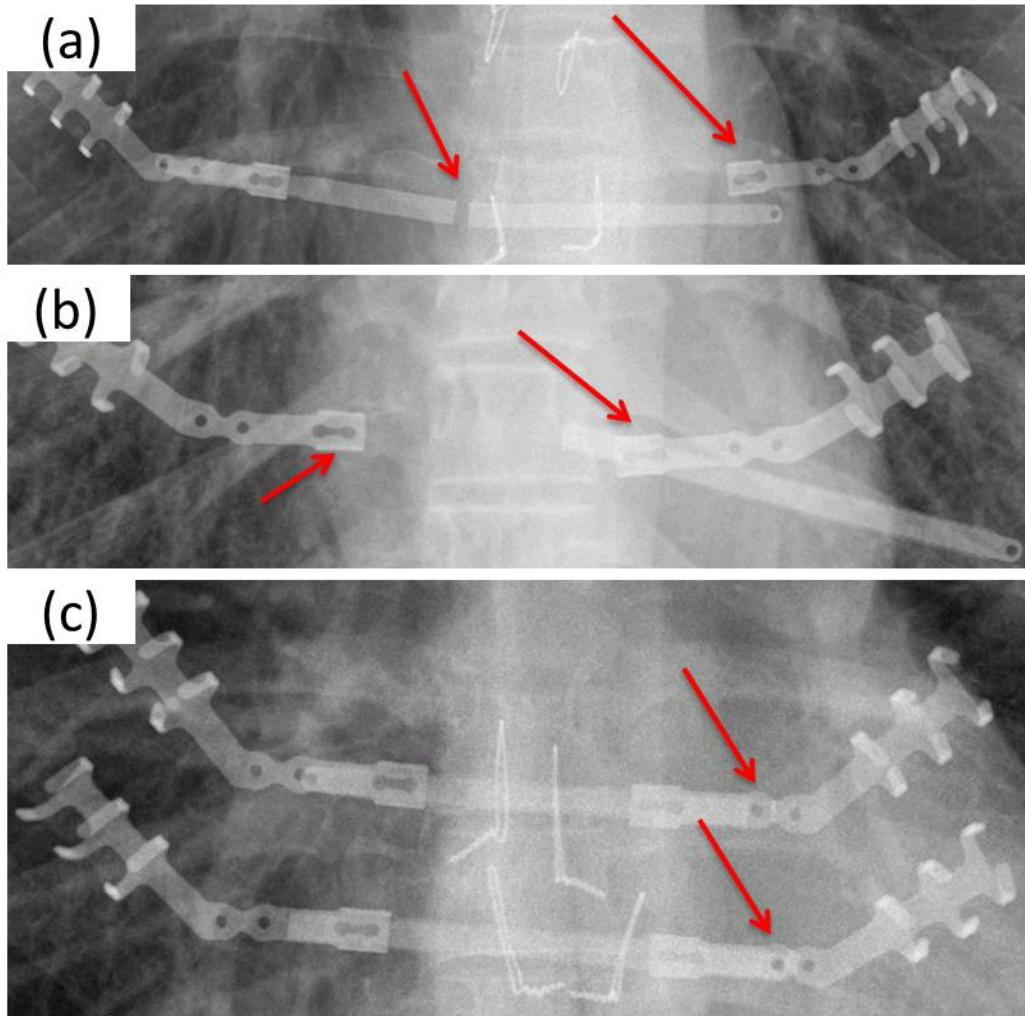


Figure 2. Single or multiple failures observed in-vivo for single or double STRATOS implants placed for Pectus correction in the span of 14th December 2011 to 18th July 2013 at UMCG. (a) and (b) also showing loose implant pieces freely floating in the cardiothoracic region.

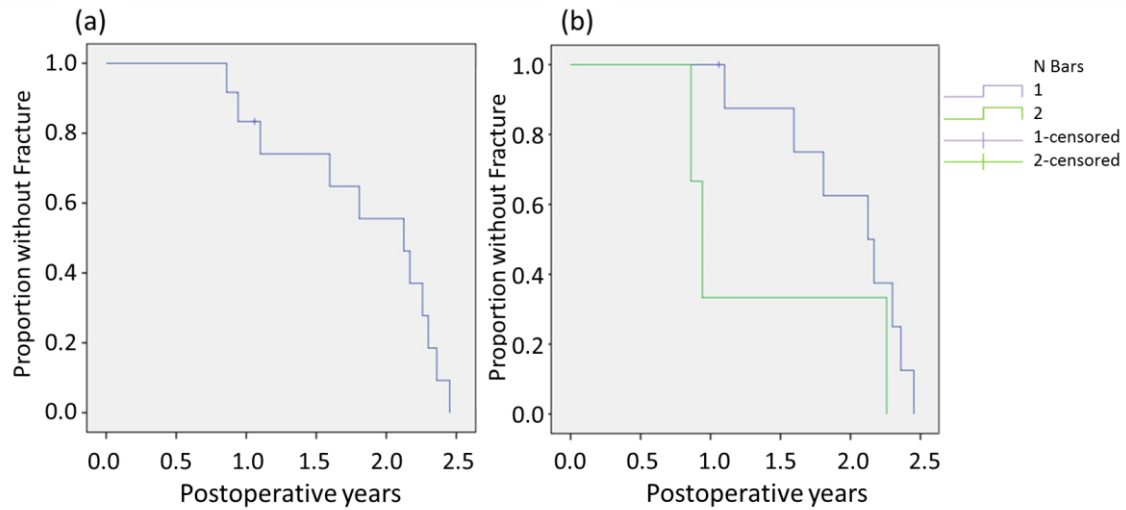


Figure 3. Kaplan-Meier plots showing the cumulative survival of the STRATOS implants in vivo (a) when all the patients were taken together and (b) when the patients carrying single or double implants were separately analysed.

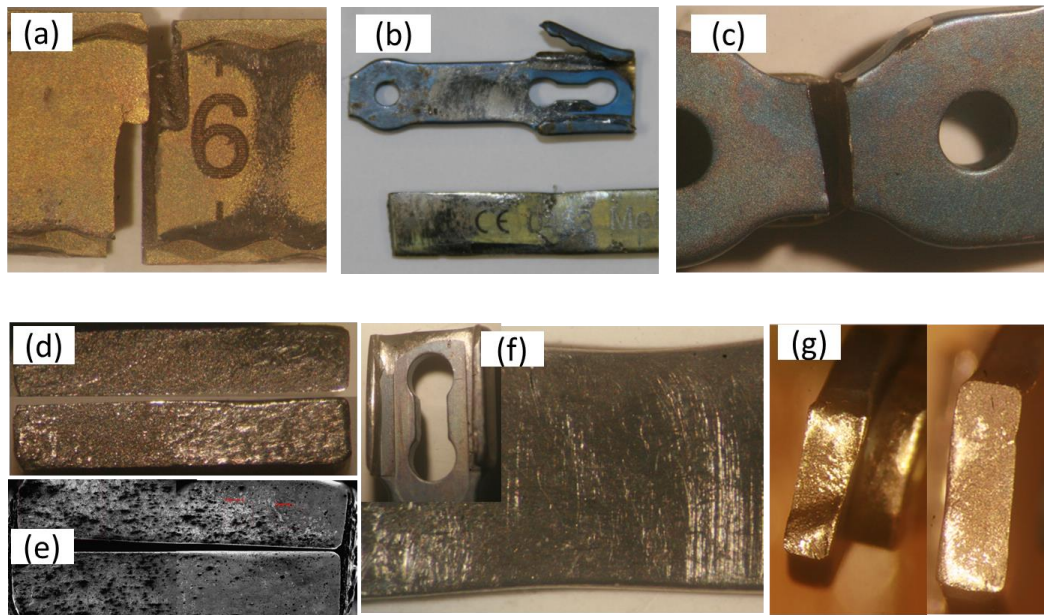


Figure 4. Three different types of failures observed (a) Clean fracture of the connecting bars, designated as F_{CB} , (b) Loosening and opening sometimes accompanied by fracture of the crimp connector leading to excessive rubbing between the connecting bar and the crimp connector, designated as L_{CC} , (c) Clean fracture observed on the lateral bar at the point of reduced cross-section and stress concentration, designated as F_{RC} , (d) optical and (e) SEM micrographs taken at 95x of F_{CB} from patient 1 showing the grainy and smooth area of the fractured surface, (f) Gross wear of the crimp connector and the connecting bar due to loosening L_{CC} in patient 1 and (g) the two sides of the clean fracture in the lateral bar for patient 8

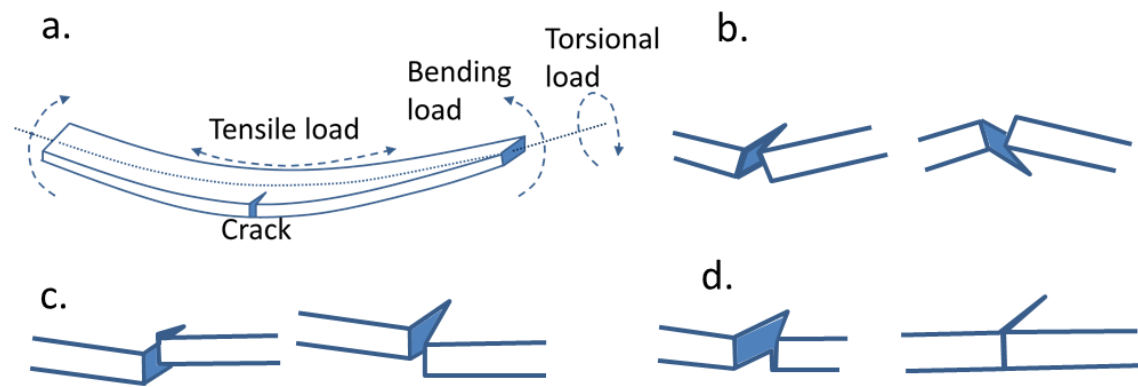


Figure 5.

Combined loading on the implant during each breathing cycle causing the fatigue crack to grow in the connecting and lateral bars of the Stratos implant.

Exaggerated crack deformation under repeated bending (a), torsional (b) and tensile (c) loads.

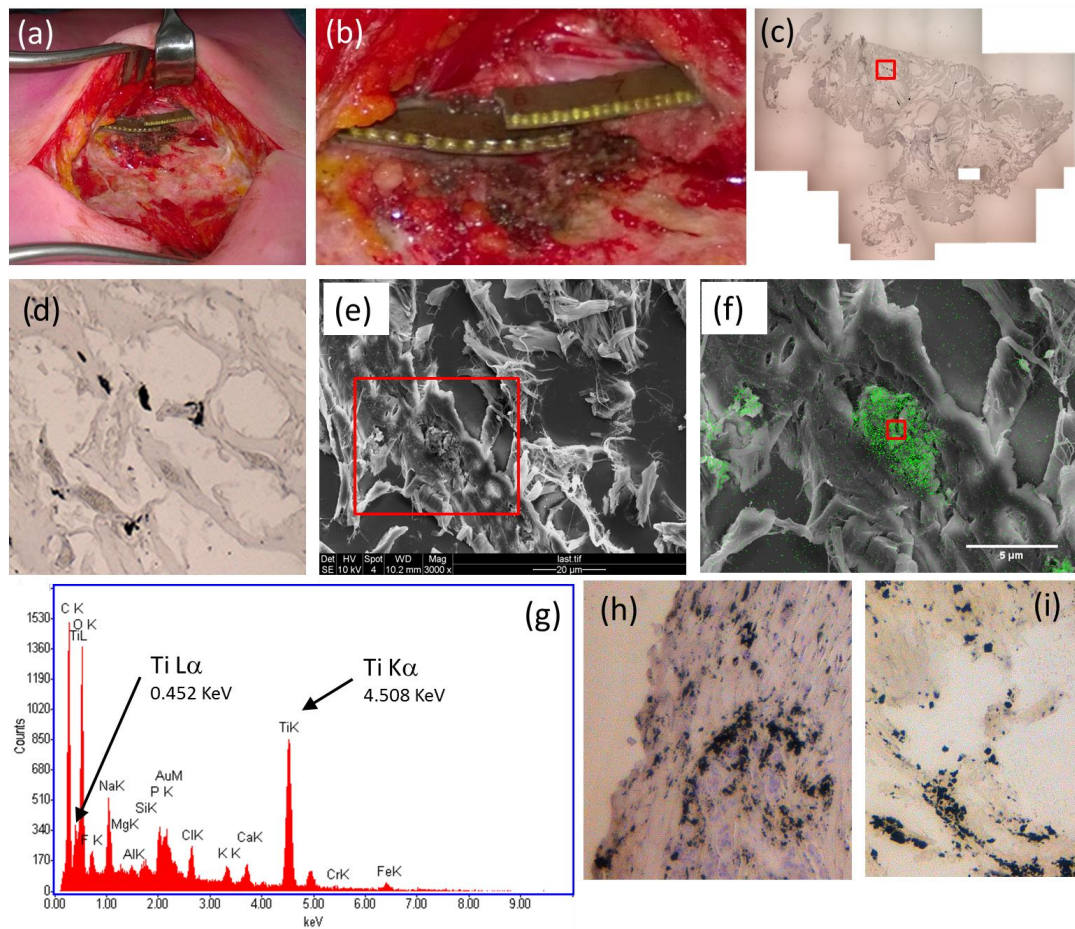


Figure 6. Presence of Ti wear debris at the failure site. (a) Preoperative failure site for patient no. 10 from Table 1, (b) Close-up of the failure site from which a biopsy was taken and fixated, (c) Haematoxylin stained section of the biopsy tissue, individual frames obtained at 10 X, (d) Optical micrograph taken at 10X from the red square shown in c (e) Scanning electron micrograph (SEM) taken from the red square shown in c clearly shows presence of individual and aggregated debris, (f) Overlay of Ti K α peak intensity map on the SE micrograph from the red rectangle shown in e, (g) High Ti peaks (K α and L α) visible on the Energy Dispersive X-ray Spectroscopy (EDX) spectrum taken at the red spot on f, (h) and (i) optical micrographs taken at 10x of respectively stained and unstained sections from biopsies taken for other failed implants, black spots showing presence of wear debris.